

REMARKS / ARGUMENTS

Claims 1-97 are pending in this application. Claims 30-88 are withdrawn in view of a previous Restriction Requirement. Applicants reserve the right to pursue these claims in a divisional application. Claims 1-27 and 29 are canceled without prejudice or disclaimer to expedite prosecution of this application. Applicants reserve the right to pursue these claims in a continuation application. Claim 28 is amended. Support for the amendments to claim 28 may be found in the specification in paragraphs [0064], [0068], [0071], [0073], [0075], [0076], and original claims 28 and 29. New claims 89-97 are hereby added. Support for these claims may be found in original claims 8-10, 15, 16, 23, 25, and 27 and in the specification at paragraphs [0073], [0075], and [0076]. In view of the amendments and remarks made herein, Applicants respectfully request reconsideration of claims 28, and 89-97.

Rejections under 35 U.S.C. § 102(b)

Claims 1-7, 10, 11, 17, 18, 24 and 27 are rejected under 35 U.S.C. § 102(b) as anticipated by Borkan *et al.* (US Pat. No. 4,935,243, hereinafter referred to as "Borkan"). Claims 1-7, 10-13, 11, 17, 18, 24 and 27 are rejected under 35 U.S.C. § 102(b) as anticipated by Borkan in view of Prasad *et al.* (hereinafter referred to as "Prasad"). Claims 1-27 are canceled in this amendment, thus obviating these rejections.

Rejections under 35 U.S.C. § 103(a)

Claims 1-29 are rejected under 35 U.S.C. § 103(a) as unpatentable over Yehuda (U.S. Pat. No. 4,851,431, hereinafter referred to as "Yehuda") in view of Chang *et al.* (U.S. Pat. No. 4,874,629, hereinafter referred to as "Chang"), Markham (U.S. Pat. No. 4,968,716, hereinafter referred to as "Markham"), The Merck Index (hereinafter referred to as "Merck"), GB1342974, and Gordeuk *et al.* (hereinafter referred to as "Gordeuk"). Applicants respectfully submit that claim 28, 29, and new claims 89-97 are patentable over the references cited.

The references cited do not teach all of the limitations of claim 28. Specifically, no combination of the references teaches a nutritional composition comprising a linolenic acid compound, a linoleic acid compound, or a combination thereof in a soft gelatin shell dosage form. No combination of the references cited teaches a nutritional composition comprising (a) a linolenic acid compound, a linoleic acid compound, or a combination thereof and (b) an omega-

3 fatty acid from fish oil in a soft gelatin shell dosage form. Furthermore, no combination of the references teaches a linolenic acid compound, a linoleic acid compound, or a combination thereof, an omega-3 fatty acid from fish oil, and iron in a soft gelatin shell dosage form

Yehuda, cited as the primary reference, teaches nutritional compositions having very specific ratios of linolenic acid to linoleic acid. From the teachings of Yehuda, one would be motivated to use the very specific ratios of linolenic acid and linoleic acid set forth, rather than using either linolenic acid or linoleic acid, or a combination thereof. Example I of Yehuda clearly shows the advantages of using a specific ratio of linolenic acid to linoleic acid in supplements to improve motor activity, pain threshold, and thermoregulation. One reading Yehuda would not be motivated to choose any ratios that may fall outside of those ranges.

There is no motivation to combine the references in such a way to enable the claimed invention. No combination of the references teaches how to combine the claimed linolenic acid compound, linoleic acid compound, or a combination thereof and an omega-3 fatty acid from fish oil with the claimed vitamins and minerals in a soft gelatin capsule form without crosslinking the gelatin, rendering the capsules useless for their intended purpose. As explained in Applicants' specification, in paragraph [0038], "the presence of iron in a soft gelatin capsule tends to crosslink the gelatin rendering it insoluble in water. This results in failure to dissolve and release its contents after ingestion." (Applicant's specification, paragraph [0038]).

Neither Yehuda, nor any combination of the references with Yehuda, provide a reasonable expectation that one could make a soft gelatin shell dosage form containing each of the Applicants' claimed nutrients. Specifically, no combination of the references teaches how to incorporate iron into a soft gelatin capsule dosage. While Yehuda states that iron, among a whole list of other things, may be included in the nutritional compositions provided therein, it offers no guidance of how iron could be added to a soft gelatin capsule without crosslinking the gelatin, thus rendering the capsule unsuitable for its intended purpose. Within the references cited, there is no recognition that crosslinking of the soft gelatin capsule may occur because of the addition of iron. Moreover, within the references cited, there is no recognition of this problem, and thus, no motivation to look for forms of iron that would not react with the gelatin causing it to crosslink and rendering the invention unusable. While GB1342974 does discuss encapsulated iron, used to prevent oxidation in foods derived from cereal grains, there is no teaching within GB1342974 that encapsulated iron may be used in soft gelatin capsule dosage

forms to prevent crosslinking of the gelatin. Nothing in Gordeuk teaches that carbonyl iron may be used with soft gelatin capsule forms without causing deleterious crosslinking of the gelatin. There is simply no motivation to combine either Gordeuk or GB1342974 with Yehuda, as there is no recognition that iron may react with a soft gelatin capsule and render it unsuitable for its purpose. As explained in MPEP 2143.01 IV., modifications of the prior art to meet the claimed invention which would have been “well within the ordinary skill of the art at the time the claimed invention was made” because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. Accordingly, Applicants respectfully submit that claim 28, as amended, and claims 89-97, dependent thereon, are non-obvious over the references cited. Applicants respectfully request withdrawal of this rejection.

Rejections Based on Non-statutory Double Patenting

Claims 1-29 are rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1-22 of U.S. Pat. No. 6,258,846, commonly owned with this application, in view of Yehuda, Chang, Markham, The Merck Index, GB1342974 and Gordeuk. Claims 1-29 are rejected on the grounds of nonstatutory obviousness-type double patenting as unpatentable over claims 1-8 of U.S. Pat. No. 7,112,609 or claims 1-23 of U.S. Pat. No. 6,576,666, both commonly owned with this application, each in view of Yehuda, Chang, Markham, The Merck Index, GB1342974 and Gordeuk. Claims 1-28 are canceled by way of this amendment. Once all other rejections have been removed, Applicants will file a terminal disclaimer if necessary

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In view of the amendments and remarks made herein, Applicants respectfully request reconsideration of this application. Applicants respectfully submit that claims 28, 29 and 89-97 are patentable over the references cited.

Respectfully submitted,

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